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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/975,308	10/11/2001	Carl Johan Friddle	LEX-0252-USA	6999

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LEXICON GENETICS INCORPORATED  
8800 TECHNOLOGY FOREST PLACE  
THE WOODLANDS, TX 77381-1160

EXAMINER

LI, RUIXIANG

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 04/15/2003

16

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Application No.

09/975,308

Applicant(s)

FRIDDLE ET AL.

Examiner

Ruixiang Li

Art Unit

1646

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED on 3/11/2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY [check either a) or b)]**

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 11 March 2003. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_.

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_.

Claim(s) objected to: \_\_\_\_\_.

Claim(s) rejected: 1-3.

Claim(s) withdrawn from consideration: \_\_\_\_\_.

8. ☐ The proposed drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
10. ☐ Other: \_\_\_\_\_

Continuation of 5. does NOT place the application in condition for allowance because: the rejection of claims 1-3 under 35 U.S.C. § 101 and 112, 1st paragraph remains.

**I. Claim rejection under 35 U.S.C. § 101**

The instant specification fails to satisfy the utility requirement set forth under 35 U.S.C. § 101 for the following reasons, as well as for the reasons set forth in the previous office actions (Paper No. 10 and Paper No. 12).

Applicants argue that the claimed nucleic acid sequences have a utility in forensic analysis because of the disclosure of a polymorphism (pages 2-3). This has been fully considered but is not deemed to be persuasive because 35 U.S.C. 101 requires disclosure of a specific, substantial, and credible utility, or a well-established utility. Such a patentable utility has to be a "real world" context of use which does not require significant further research. Since the instant disclosure fails to disclose the population that polymorphic marker distinguishes, significant further research would be required to identify or reasonably confirm a "real word" context of use. Thus, the asserted utility of a polymorphic marker for forensic analysis is not considered specific and substantial.

Applicants' arguments regarding (i) the homology of SEQ ID NO: 9 with GenBank AB065623 (top of page 4), (ii) 60% of the pharmaceutical products currently being marked by the entire industry target GPCRs (bottom of page 4), (iii) use of DNA chip for assessing gene expression and for gene mapping (pages 5-6), and (iv) the requirements set forth in the action for compliance with 35 U.S.C. § 101 do not comply with the requirements set forth by the PTO itself for compliance with 35 U.S.C. § 101 (page 7), have been addressed in the previous office action in Paper No. 12.

**II. Claim Rejections Under 35 U. S. C. §112, 1st Paragraph**

Claims 1-3 are rejected under 35 U. S. C. 112, 1st paragraph. Specifically, since the claimed invention is not supported by either a specific, substantial, and credible utility, or a well-established utility, one skilled in the art clearly would not know how to use the claimed invention. The applicants' arguments about the patentable utility of the claimed invention has been fully considered but is not deemed to be persuasive for reason set for the above.

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